REMARKS

I. Status of Claims

Claims 25-28, 31-39 are pending in the application, among which claim 32 is withdrawn from consideration and the remaining claims were examined in the present Office Action.

By this amendment, Applicant has cancelled claims 25 – 28, 31, 33, and 39. After entry of the amendment, claims 32, and 34 – 38 are pending in the application.

II. Amendment of Claims

Claim 34 has been amended to restrict the "α-amino acid" to "neutral α-amino acid." Claims 35 and 36 have been amended to recite specific neutral α-amino acids. Support for the amendments can be found in the specification as filed, including the claims (see, for example, original claims 26, 27, and 36, where specific neutral α-amino acids are disclosed.) Therefore, the amendments add no new matter. The cancellation and amendments of the claims are not for patentability reason but solely for the purpose of expediting the allowance of the application. Applicant preserves the right to pursue the cancelled subject matter in continuing applications.

III. Claim Rejection under 35 U.S.C. §112

Claims 25-28, 31, and 33-39 are rejected under 35 U.S.C. §112, first paragraph, allegedly for lack of enablement. The Examiner has admitted that the specification is "enabling for the neutral α-amino acids," but alleged that it does not provide enablement for "an α amino acid". Applicant has cancelled claims 25-28, 31, and 39, which rendered the rejection to these claims moot. Claims 33-38 as amended no longer recite "α amino acid;" rather, they now recite "neutral α-amino acids" or specific neutral α-amino acids. As the Examiner has admitted, the specification is enabling for neutral α-amino acids; therefore, claims 33-38 satisfy the enablement requirement.

Claims 25-28, 31, 33, and 39 are rejected under 35 U.S.C. §112, first paragraph, allegedly for failing to comply with the written description requirement. The claims at issue have been cancelled; therefore, the rejection is mooted.

IV. Claim Rejection under 35 U.S.C. § 102

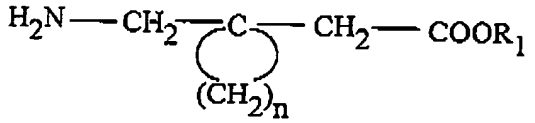
Claims 25-27, 29, and 31 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Woodruff (US 5,084,479). Applicant believes that the Examiner's rejection of claim 29 is in error because this claim was cancelled by the previous amendment and, thus, is no longer pending in the application. Accordingly, Applicant does not address the rejection to claim 29 here. Claims 25-27, and 31, as amended, are drawn to a solid composition comprising gabapentin and a neutral α-amino acid. Woodruff does not disclose a solid composition comprising gabapentin and a neutral α-amino acid. It does not even relate to solid compositions. Rather, as the Examiner has admitted, Woodruff discloses a solution. Because Woodruff does not disclose all the elements of the claims at issue, it does not anticipate them.

Claims 34, 38, and 39 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Augart et al. (US 6,054,482). The Examiner states that Augart et al. disclose a pharmaceutical composition consisting essentially of "gabapentin in the free amino acid and adjuvants" and that "since amino acids are alpha (position of the amine) and L (stereochemistry) amino acid in nature, the referenced composition anticipates the claimed invention." Applicant respectfully submits that Augart et al. do not anticipate the claimed invention because they do not teach all the elements of the claim invention. Elements of the claimed composition include "4-amino-3-substituted-butanoic acid derivative" and "neutral α-amino acid." While Augart discloses a composition containing gabapentin, it does no disclose a composition that contains a neutral α-amino acid in addition to gabapentin.

The Examiner's basis in alleging that Augart discloses a composition that contains an α-amino acid in addition to gabapentin is that Augart discloses a pharmaceutical composition consisting essentially of "gabapentin in the free amino acid." Applicant does not believe that the Examiner's above allegation is supported by the cited reference. Augart et al. do not disclose gabapentin in the "free amino acid." Rather, they refer to gabapentin in its "free amino acid form." In other words, they refer to a physical form of gabapentin, namely gabapentin in the form of free amino acid (as apposed to salt or any other form). In this regard, the Examiner's attention is respectfully drawn to the bottom paragraph of column 3 (which discusses salt and free amino acid forms of gabapentin) and claim 7 (which recites "gabapentin in the free amino

acid, crystalline anhydrous form.") of the cited reference. Therefore, the terms "gabapentin" and "free amino acid" as used in the cited reference refer to one agent, not two separate agents.

The Examiner further alleges that "since amino acids are alpha (position of the amine) and L (stereochemistry) amino acid in nature, the referenced composition anticipates the claimed invention." First of all, as explained above, the cited reference does not disclose a composition containing gabapentin in combination with an α-amino acid. Second, even if the cited reference refers "amino acids," it does not follow that it discloses "α-amino acids." The term "amino acid" is known in the art to generically refer to any molecule that contains both amine and carboxyl functional groups. There is an infinite number of possible positions at which the amine and carboxyl functional group may be attached in the molecule. In contrast, and as the Examiner has recognized, the term "α-amino acid" refers to a specific sub-group of amino acids that have an amine group at a particular position, namely, amino acids in which the amino and carboxyl groups are attached to the same carbon atom. Therefore, contrary to the Examiner's assertion, "amino acids" are not "alpha [ ] amino acid in nature." Further contrary to the Examiner's assertion, the "amino acids" disclosed in Augrat et al. are clearly not "α-amino acid." Augart et al. disclose cyclic amino acids of the following specific formula



(See column 1, lines 43-50) The amine and carboxyl groups of the amino acids represented by this formula are not attached to the same carbon but are separated by three carbon atoms. Because Augrat et al. do not teach the element of "α-amino acid," they can not anticipate the claimed invention.

V. Claim Rejection under 35 U.S.C. §103

A. Claims 25-28, 31, 33, and 35-37 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Augart et al. (US 6054482) in view of Robson et al. (US 4,126,684), and further in view of Costa et al. (US 5,248,678) and Bays et al. (WO 96/11690). Claims 25-28, 31, and 33 have been cancelled by this amendment; therefore, the rejection to these claims is mooted.

With respect to claims 35-37, Applicant respectfully submits that, for reasons of record and further reasons detailed below, the rejection is improper.

The primary reference cited by the Examiner is Augart et al. According to the Examiner, Augart et al. disclose a pharmaceutical composition consisting essentially of gabapentin in free amino acid and adjuvants. The Examiner has admitted that Augart et al. do not teach the inclusion of alpha amino acid, nor amount of alpha amino acid, in the composition. To remedy this defect, the Examiner cited Robson et al. as allegedly disclosing a composition containing baclofen and glycine, and further cited Costa et al. allegedly to demonstrate "the art recognized functional equivalent of gabapentin and baclofen as GABA agonists." According to the Examiner, Bays et al. is being supplied to demonstrate the routine knowledge of preparing various dosage forms including solid and liquid forms. The Examiner concluded that it would have been obvious to include alpha amino acid such as glycine in the composition of Augart et al. in view of the alleged teaching of Robson et al. and Costa et al.

Applicant respectfully submits that, when applying 35 USC 103, the Examiner is required to adhere to the following patent law tenets: (A) The references must be considered as a whole and must suggest the desirability of making the combination; (B) There must be a reasonable expectation of success of modifying the references' teaching; and (C) The claimed invention must be considered as a whole. MPEP 2141; Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 229 USPQ 182, 187 (Fed. Cir.1986). Applicant believes that, for reasons of record and additional reasons detailed below, the claimed invention would not have been obvious under these requirements.

A. No Suggestion of the Desirability of Making the Modification

The Examiner has the initial burden to provide a suggestion of the desirability of modifying or combining the references (MPEP 2142). Applicant submits that the Examiner has not met this burden. The Examiner has not suggested any desirability of modifying the composition of Augart et al. by incorporating an alpha amino acid in the composition to arrive at the claimed invention. The Examiner asserted that "one of ordinary skill in the art would have expected that the incorporation of glycine as alpha amino acid would not change the physicochemical property of Augart composition." Applicant submit that the Examiner's assertion is not supported by any of the cited references because none of the references discloses

what effect the inclusion of glycine might have on the physicochemical property of the composition of Augart et al.; nor has the Examiner pointed to any part of any reference as support for the assertion.

Applicant further submits that, contrary to the Examiner's assertion, Augart et al. actually teach that it can not be reasonably expected that incorporation of glycine would cause no change in the physicochemical property of the composition of Augart et al. Specifically, Augart et al. teach that gabapentin or similar compounds tend to form lactam easily during storage and, therefore, it is very difficult to maintain its stability in pharmaceutical compositions. (columns 3 and 4) Augart et al. further teach that "[i]t was difficult to determine the cause for the deficient stability" (column 3, lines 55-59) and, in the case of investigations of final pharmaceutical forms, "the cause of the lactam formation was apparently also the catalytic effects of adjuvant materials which also did not follow any recognizable logic." (column 4, line 58-64, emphasis added) Thus, Augart et al. clearly teach that it is totally unpredictable whether a particular adjuvant material will affect the stability of gabapentin in the composition. In order to establish which adjuvant materials affect the lactam formation, Augart et al. teach that "laborious serial investigations had, therefore, to be carried out." (column 4, lines 62-64). No information about glycine or any other amino acid is disclosed in Augart et al. Considering the disclosure of Augart et al. as a whole, a person skilled in the art would have no reason to reasonably believe that incorporation of glycine would not change the stability or any other physicochemical property of the gabapentin in the composition of Augart et al.

Moreover, even if, arguendo, incorporation of glycine would indeed be expected to cause no change in the physicochemical property of the composition of Augart et al., it in no way suggests that modifying the composition wound be desirable. Without a suggestion of the desirability, a prima facie obviousness can not be established.

The Examiner has further alleged that "since the equivalence of gabapentin and baclofen as GABA agonist is well known in the art, the selection of any known GABA agonists from limited examples of Costa to arrive at the claimed invention would be within the level of ordinary skill in the art." This same allegation was made in the previous office action. Applicant wishes to reiterate the previous response to this allegation, as well as submit the following additional remarks.

Applicant respectfully submits that the fact that a claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient to establish a prima facie case of obviousness; there still must be a motivation to combine the teaching of the references. MPEP 2143.01. Applicant submits that the Examiner has not suggested such a motivation. Even assume, arguendo, that gabapentin and baclofen are recognized functional equivalents as GABA agonists, that equivalency does not provide the requisite motivation to incorporate glycine in the composition of Augart et al. Augart et al. teach that the adjuvant materials for inclusion in the pharmaceutical preparation of gabapentin must be carefully selected in order to reduce lactam formation. Specifically, they teach that the lactam formation was apparently also caused by the "catalytic effects of adjuvant materials which also did not follow any recognizable logic." (column 4, line 58-64). In order to keep gabapentin lactam in a pharmaceutical preparation to an acceptable level, Augart et al. teach that "the precise choice of adjuvant materials" must be practiced in order to suppress the catalysis of the lactam formation. (column 5, lines 17-33). None of the cited references suggests whether glycine will affect lactam formation in compositions containing gabapentin or baclofen. Therefore, in view of the teaching of the references, a person skilled in the art would not have been motivated to choose glycine for incorporation in the Augart composition.

Finally, the Examiner has alleged that "one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about," citing MPEP 2140.01(a). Applicant does not believe that the Examiner's position has any basis in MPEP or patent law. A finding that a reference is in the same technical fields and pertinent to the problem which applicant concerns about merely shows that the reference is analogous prior art and thus may be relied on as a basis for rejection. It in and by itself does not establish any element of the prima facie case of obviousness, including the requisite "motivation." Rather, it just begins the inquiry into whether a skilled artisan would have been motivated to combine references. In this regard, the Examiner attention is respectfully drawn to MPEP 2141.01(a) and In re Kahn, 78 USPQ2d 1329 (CAFC 2006).

B. No Reasonable Expectation of Success

Applicant respectfully submits that the references provide no reasonable expectation of success to modify Augart et al. to arrive at the claimed invention. As disclosed in the specification, one particular problem with which Applicant were concerned is degradation of gabapentin into toxic corresponding lactam in a finished product (see, for example, "Background of the Invention"). Applicant has made earnest studies to solve the problem and have found that the degradation of gabapentin to form lactam can be prevented by addition of an alpha amino acid (see "Summary of the Invention"). Further, as noted above, Augart et al. teach that lactam formation was apparently also caused by the catalytic effects of adjuvant materials which also did not follow any recognizable logic (column 4, line 58-64) and that, in order to keep gabapentin lactam in a pharmaceutical preparation to an acceptable level, precise choice of adjuvant materials is required. (column 5, lines 17-33). Because none of the cited references teach or suggest that an alpha amino acid would reduce gabapentin lactam formation, there would be no reasonable expectation of success to incorporate an alpha amino acid to the composition of Augart et al. to arrive at the claimed invention.

C. Nonobviousness of the Claimed Invention Considered as a Whole

In determining obviousness the Examiner is required to consider the claimed invention as a whole, which in turn requires looking not only to the subject matter which is literally recited in the claim in question "but also to those properties of the subject matter which are inherent in the subject matter and are disclosed in the specification." In re Antonie, 559 F.2d 618, 619, 195 U.S.P.Q. 6, 8 (C.C.P.A. 1977). The specification discloses that pharmaceutical preparations containing gabapentin is difficult to prepare because the active ingredient readily undergoes degradation to form corresponding lactam and that it is necessary in manufacturing a pharmaceutical preparation of gabapentin to prevent the formation of the lactam. (See "Background of the Invention"). The specification further discloses that the claimed invention possesses superior storage stability. The comparative data disclosed in the specification show that addition of alpha amino acid to the composition reduced the formation of the corresponding lactam, thus stabilizing the composition. The stability of the claimed composition is a property inherent in the claimed invention and is disclosed in the specification. Therefore, the stability is part of the claimed invention as a whole and should be considered in determining whether or not the claimed invention is obviousness. As explained above, none of the cited references suggest

that pharmaceutical composition containing an alpha amino acid and gabapentin would have increased stability in terms of reduced lactam formation. Further, in view of the teaching of Augart et al. that the cause of lactam formation in the pharmaceutical compositions was apparently also the catalytic effects of adjuvant materials in the compositions, the reduced lactam formation in the claimed invention is not only a superior property, but also unexpected. Accordingly, the claimed an invention considered as a whole would not have been obvious.

VI. Double Patenting

In the previous Office Action the Examiner rejected claims 25-31 and 33 under the judicially created doctrine of double patenting over claims 28-39 of co-pending US Application No. 09/674,819. Applicant argued in the previous reply that the rejection is improper because US Application No. 09/674,819 has not yet issued as patent and no actual double patenting rejection may be properly made over claims of a co-pending application. This rejection is not maintained in the present Office Action and, accordingly, is considered by Applicant as being withdrawn. Applicant has noted that in the present Office Action, the Examiner provisionally rejected claims 25-28, 31, and 33-39 under the judicially created doctrine of double patenting over the same co-pending application. Applicant will address this provisional double patenting rejection pending future prosecution of the two co-pending applications.

VII. Concluding Remarks

In view of the amendments and the foregoing remarks, Applicant respectfully requests reconsideration of the matter, the withdrawal of all the rejections, and timely issuance of a Notice of Allowance.

Respectfully submitted,

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Austin W. Zhang (Reg. No. 48,061)
Warner-Lambert Company LLC
2800 Plymouth Road
Ann Arbor, MI 48105
Customer No. 28880

Tel: (734) 622-5035
Fax: (734) 622-1553